

REMARKS

This is in response to the Final Office Action dated August 25, 2005 rejecting original claims 28-49.

The specification has been amended in the Cross-references to Related Applications section to correct a typographical error. Applicant thanks the Examiner for pointing out this oversight.

No changes have been made to the claims. Claims 28-49 are thus pending. It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims under examination be allowed.

Rejection Under 35 U.S.C. §102(e)

Claims 28-49 stand rejected under 35 U.S.C. §102 (e), as allegedly being anticipated by US Patent No. 6,405,732 ("the '307 patent" hereinafter). The rejection is respectfully traversed for the reasons set forth below.

The standard for anticipation under 35 U.S.C. §102 is that each and every element of the claim must be found in the cited reference. *In re Marshall*, 198 USPQ 344 (CCPA 1978).

As a preliminary matter, the Office Action states that the language of claim 28 directed toward conditions selected to initiate regrowth of a mucosal layer is "intended use" language. The Office action goes on to state that intended use language holds no patentable weight in system claims. Applicant disagrees with the Examiner's characterization of claim 28. Claim 28 recites a system for treating mucosal tissue in an esophagus, said system comprising:

an elongated member;

an energy delivery structure deployable from the elongated member and adapted to deliver energy to at least a portion of a circumferential section of the mucosal lining of the esophagus; and

means for delivering energy through the delivery structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer.

As such, Applicant submits that Claim 28 is a means plus function claim and not simply a system claim. This position is supported since claim 28 recites a means (a system comprising an elongated member; an energy delivery structure and a means for delivering energy through the delivery structure) adapted to perform a function (initiating regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer). Accordingly, claim 28 is not simply a system claim including intended use language, but rather a patentable means plus function claim.

Turning now to the rejection of claim 28 in view of the '307 patent, Applicant submits that the reference fails to teach each and every element of claim 28 or its dependent claims. The '307 patent teaches a procedure for the treatment of aberrant electrical sites in the lower esophageal sphincter (LES) and stomach as a means for treating GERD. See col. 2, lns. 24-26; col. 3, lns. 34-41.

The method described in the '307 patent involves the ablation of the nerve fibers and/or pathways leading from gastric receptors to eliminate nerve impulses going from these receptors.

"[t]he ablation is done in or near the cardia and/or LES." See col. 7, lns. 13-26; col. 7, ln. 47. Using the method described in the '307 patent, the lesions are located in the smooth muscle layer of the sphincter at a depth of 1-4 mm from the interior surface of the sphincter wall. See col. 17, lns. 1-4. The '307 patent teaches control of the location of the lesions by actually penetrating the LES smooth muscle using needle electrodes. See col. 13, lns. 16-33; Figures 12-17, 23, 26, 27.

As discussed above, the present application recites in claim 28 a system for treating mucosal tissue in an esophagus comprising an elongated member, an energy delivery structure deployable from the elongated member and adapted to deliver energy to a circumferential section of the mucosal lining of the esophagus and a means for delivering energy through the energy delivery

structure under conditions selected to initiate regrowth of a mucosal layer without substantial injury to a submucosal layer underlying the mucosal layer. In contrast, the '307 patent describes delivering energy to nerve fibers while penetrating the smooth muscle of the LES. The '307 patent teaches control of the location of the lesion by using needle electrodes. By choosing the location of the needle electrode in the LES, and consequently, choosing the location of the lesion, the '307 patent teaches creation of a buffer zone in the smooth muscle to prevent thermal damage to the mucosa. See col. 16, lns. 33-35. Thus, by teaching that the lesions are centered to prevent damage to the mucosa, the '307 patent teaches away from the present invention. Hence, each and every element of the present invention as recited in claim 28 is not taught or suggested by the '307 patent.

For the foregoing reasons, Applicant respectfully requests that the rejection of claim 28 be withdrawn. Because the claims dependent from claim 28 (claims 29-49) include further limitations in addition to those recited in claim 28, Applicant believes that all depending claims are also allowable over the cited reference of record. Reconsideration of this rejection is respectfully requested.

Notwithstanding the above, in respect to claims 34-39, Applicant submits that the '307 patent fails to disclose each and every element of these claims and they should be found allowable.

Claim 34 which depends from claim 33, recites a system wherein an electrode array comprises bipolar electrode pairs formed over at least a portion of the outer surface of a balloon, wherein the spacing between electrodes is no more than 3 mm. With respect to electrodes arranged over the surface of a balloon, the Office Action states (see page 4, last para.) that the '307 patent shows in figure(s) 18 (a-d) a feature numbered (50) that "looks like a balloon, which is referred to [elsewhere] in the patent as element 55." The Action further states (see page 4, last para.) that figure(s) 18 and col. 11:65-67 of the reference disclose variously aligned bipolar or monopolar electrode arrays. Applicant submits that taken together these alleged disclosures do not amount to a disclosure of the subject matter recited in claim 34. This position is supported since the electrode distributions illustrated in figure(s) 18 (a-d) and disclosed in the specification are plainly in respect to a mapping assembly (20) or basket assembly (50), not a balloon. See col. 14, lns. 33-38; figure(s)

18 (a-d). Nowhere is a balloon disclosed in relation to the illustrations shown in figure(s) 18 (a-d). Furthermore, electrodes arranged over the surface of a balloon are not disclosed elsewhere in the reference. As such, each and every element of the present invention as recited in claim 34 is not taught or suggested by the '307 patent. Likewise, claims 35-36 which depend from claim 34 are similarly unanticipated by the reference. Similarly, claims 37 and 38 which recite systems having electrodes formed over at least a portion of the exterior or interior surface of a balloon respectively, are not anticipated by the reference.

Applicant submits that Claim 39 is not anticipated by the '307 patent since the reference fails to disclose the recited limitation "wherein the balloon is inflatable with a conductive medium to form a monopolar electrode." The '307 patent does not disclose inflation of a balloon with a conductive medium. Rather, the reference teaches the infusion of highly conductive fluid such as electrolytic solution into tissue to produce an enhanced electrode for treating a greater volume of tissue. See col. 12, lns. 12-30; figure 11a. The reference teaches that delivery of an electrolytic solution to a treatment site is achieved through various apertures including apertures 64 in combination with arm lumens 58 and shaft lumens 36. See col. 10, lns. 49-53; figure 6a. However, it is neither taught nor suggested that delivery of such a solution is by way of inflation of a balloon with a conductive fluid. Accordingly, since each and every element is not found in the reference, claim 39 is not anticipated.

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CONCLUSION

For the reasons set forth above, Applicant submits that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims under examination in this application is earnestly solicited.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 28791-702.502).

Respectfully submitted,

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